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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/985,820	11/06/2001	David Vale	08157.0014	4546

7590 10/18/2004

Finnegan, Henderson, Farabow,  
Garrett & Dunner, L.L.P.  
1300 I Street, N.W.  
Washington, DC 20005-3315

EXAMINER
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HO, UYEN T

ART UNIT	PAPER NUMBER
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3731

DATE MAILED: 10/18/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/985,820

Applicant(s)

VALE ET AL.

Examiner

(Jackie) Tan-Uyen T. Ho

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 6/15/04.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-61 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-61 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

## DETAILED ACTION

### *Response to Arguments*

1. Applicant's arguments have been considered but are moot in view of the new ground(s) of rejection.

### *Claim Rejections - 35 USC § 103*

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

1. Claims 1-61 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ambrisco et al. (6,007,557) in view of Ding et al. (5,879,697). Ambrisco et al. disclose a filter system as claimed and suggest the filter membrane may be coated with a non-thrombogenic material for example Heparin (col. 3, lines 10-30 and see the detail section for the filter system embodiments). Although, Ambrisco et al. fail to disclose the thickness of the coating as claimed. Ding et al. (5,879,697) disclose a drug-releasing coating, the coating is applied depending upon the coating thickness desired and the purpose of adjusting the thickness of the coating is for time control and release the drug (col. 8, line 52 to col. 9, line 6). Therefore, it would have been obvious to one having ordinary skill in the art to apply the coating on the filter as disclosed by Ambrisco et al. such that the coating within the range as claimed in order to control and release the drug at a desired level.

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In regard to hydrogel or hydrophilic materials, it is well known to provide a layer including a hydrophilic polymer or hydrogel for control and release drug (See competent documentary evidence, Thompson et al. reference, col. 8). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to employ a hydrophilic polymer or hydrogel layer into Ambrisco et al. in view of Ding et al. in order to provide a better control and release non thrombogenic material.

In regard to claim 12, a Product-by-Process claim, this claim is not limited to the manipulations of the recited steps.

In regard to different stiffness of filter sections, Ambrisco disclose filter elements having different stiffness for example the filter in figure 35-36 of Ambrisco, the different stiffness between sections that having expanding frame 313 and sections (310) that do not have the expanding frame (313), a proximal inlet portion at the base (312) and the distal outlet portion at the sections (313). Note: "laminate construction" does not impose any structural limitations on the claims distinguishable over the device of Ambrisco in view Ding et al.. Examiner considers a filter having laminate construction being a filter with two or more layers that are attached to each other.

2. Claims 1-61 are rejected under 35 U.S.C. 103(a) as being unpatentable over Daniel et al. (6,171,327) in view of Thompson et al. (5,834,449) further in view of Ding et al. (5,879,697). Daniel et al. disclose a filter as claimed except for a presence of the thickness of the coating as claimed and coating including hydrophilic or hydrogel material. Thompson et al. teach a coating layer including hydrophilic materials for use in control and release drug on a medical device such as filter (col. 8). Hydrogel is a well-

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known hydrophilic material for use in control and release drug on medical surface. Ding et al. teach a drug-releasing coating wherein the coating is applied depending upon the coating thickness desired and the purpose of adjusting the thickness of the coating is for time control and release the drug (col. 8, line 52 to col. 9, line 6). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to employ the material disclose by Thompson et al. or hydrogel and adjusting the thickness of the coating in order to control and release the non thrombogenic material or drug a desired level. Doing so would meet all the limitation as claimed.

3. Any inquiry concerning this communication or earlier communications from the examiner should be directed to (Jackie) Tan-Uyen T. Ho whose telephone number is (703) 306-3421. The examiner can normally be reached on MULTIFLEX Mon. to Sat.. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, ANHTUAN or NGUYEN can be reached on 703-308-2154. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system.



(Jackie) Tan-Uyen T. Ho  
Patent Examiner  
Art Unit 3731

October 12, 2004